Automated Commercial Environment—Requirements Recommendation

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Requirement Number:	ITD-023 (formerly ITD-007, ITD-008, and ITD-009	**Scheduled Release:**	2, 3, 4, 5, 6, 7
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Subject Matter:	**FDA: Cargo Exam/Entry Summary/Arrival Release**		

Requirement

Cargo Exam

With the advent of the new Bioterrorism Act (BTA) regulations there now exists a two-tiered FDA clearance process under sections 21 CFR 801(a) and 801(m) for imports of food and food related products for human and animal consumption. Under the new regulations, expanded shipment and carrier required data elements must now be submitted to FDA on these types of shipments anywhere from a proposed 30 minutes prior up to a maximum 5 days prior to shipment arrival depending on the specific mode of transportation. Information is submitted electronically via ABI or FDA's web based system (PNSI). Based on this information FDA will determine whether a bioterrorist threat exists under section 801(m) and will notify Customs and Border Protection (CBP) to hold the shipment prior to crossing the border. In addition, once the entry information is submitted to FDA as required for admissibility, they will then determine whether any other admissibility risks exists under 801(a) and will notify the importer to hold the shipment prior to distribution if required.

For FDA regulated commodities other than those described above, the required data information is submitted to FDA via ABI (and on to FDA's internal OASIS system) per current procedures. FDA then determines whether any other admissibility risks exist under 801(a) and will notify the importer to hold the shipment prior to distribution if required.

Because no specific commodity information is required in data submitted at time of shipment arrival for FAST shipments that are not regulated under the BTA, compliance checks are based on a random sample across all of that importer's FAST shipments. In future, if additional expedited status and/or benefits programs are applied for and approved it is also possible that a reduced number of specific data elements may be required at time of entry summary under those programs for commodities that are not regulated under the BTA and compliance checks may be based on a random sample across all of an approved importers/exporters shipments. When an exam is required, however, additional cargo examination data would be collected via the ABI system according to FDA requirements.

Entry filers will provide electronic cargo exam data within one hour of an electronic request. Based on its analysis of the cargo examination data FDA may elect to perform its own cargo examination on shipments selected for random compliance examinations.

Entry Summary

For FAST shipments not regulated by the BTA and released without cargo examination, specific commodity information is not submitted until entry summary data is filed. In this case, FDA data for reported commodities will be collected in the entry summary.

Arrival/Release

In order to avoid delays FDA staff will be available to make cargo release decisions at all hours when a motor freight port is open.

NEXT STEPS: ITDS Committee members will follow up to determine the future vision of CBP in regards to integration of PGAs and obtaining multiple PGA approvals for expedited status and/or benefits programs (e.g., CTPAT, FAST). ITDS committee members will discuss reduced data requirements for shipments that are not covered under the BTA regulations and the operational procedures that may be required for such a benefit.

Develop a plan to address the submission of additional cargo exam data elements electronically via ACE. Continue to follow the FDA/CBP plan for risk analysis and timing requirement integration and provide assistance in developing a plan for further integration as needed.

Define a mechanism that will allow trade to quickly address any problems with any authorized expedited import/export process.

Business Need

To provide importers/exporters that are regulated by the FDA and do not have commodities that are currently covered under the BTA regulations with expedited import/export benefits under authorized expedited processes and/or benefits programs. Permits electronic reporting of data required by FDA. Permits expedited processing of shipments even when FDA personnel may not be physically available at the port of entry.

Technical Need

Requires both the PGA and the importer's participation in the current ACE system. Potential systems upgrades and/or changes in the PGA's internal systems to accommodate their particular requirements for any appeals process that is implemented. Potential coordination with CBP's internal system requirements. Coordination with CBP personnel to allow for 24/7 release decision making for FDA regulated commodities.

Benefits

Allows expedited processing of legitimate known shipments and efficient designation of resources towards unknown, higher risk shipments.

Risks

PGAs may not wish to participate in an account based risk management environment or may not wish to spend resources integrating into the ACE system. Mandatory participation of all identified PGAs in the ACE system will remove this risk, if enacted.

PGA involvement in current and future expedited programs that may be developed could potentially require internal PGA business process changes that may, in turn, require legislative updates to accommodate those new processes.

Related Subcommittees

Accounts
Entry
Legal Policy

Priority: **Critical** ☐ **High** ☐ **Medium** ☐ **Low** ☐